**REMARKS:**

In response to the Office Action mailed August 19, 2008, claims 54, 57, and 64 have been canceled without prejudice, and claims 1, 32, 37, 48, 55, 56, 74, 96, 113, 116, 117, 119, and 125 have been amended. Accordingly, claims 1-5, 9, 10, 16, 21, 29-32, 34-37, 41-44, 46-53, 55, 56, 74, 96-107, 113, 114, 116-130 are pending, with claims 3-5, 35, 36, 42-44, 46-50, 55, and 97-107 withdrawn from further consideration as directed to non-elected species. Support for the amendments may be found throughout the specification, e.g., in paragraphs [0116], [0149], [0150], [0189], and [0190], and the drawings, e.g., in FIGS. 49-55 and 88-90. No new matter has been introduced.

In the Office Action, claims 96, 113, 114, 119-123, 125, 126, and 128-130 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,241,765 ("the Griffin et al. reference") and claims 1, 2, 9, 10, 16, 21, 29-32, 34, 37, 41, 51-54, 56, 74, 116-118, 124, and 127 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Griffin et al. reference in view of U.S. Patent No. 6,066,160 ("the Colvin et al. reference") and U.S. Patent No. 4,548,202 ("the Duncan reference"). Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning to the § 102(b) rejections, the Griffin et al. reference discloses a prosthetic heart valve 10 that includes an annular valve body 14 with pivoting leaflets 16, 18, and a stiffening ring 29. Col. 2, lines 59-61. The stiffening ring 29 includes a shoulder 57 that includes recesses 81 or openings 96 adapted to receive a fastener 90, i.e., a staple 79 or pin 91. Col. 4, lines 29-32, 46-48, col. 5, lines 19-24. The fasteners 90 do not have lengths such that the stiffening ring 29 can be

parachuted down the fasteners 90. Instead, the pins 91 are inserted through the patient's heart tissue from below and into the openings 96 until barbs 94 extend through the opening 96 and engage an upper surface 82 of the shoulder 57. Col. 5, lines 24-28.

The Griffin et al. reference actually teaches against parachuting prosthetic heart valves into position, arguing that suturing takes significant time and skill by a surgeon and that the disclosed devices solve or reduce the problems associating with such suturing. Col. 1, lines 31-40. In contrast, the Griffin et al. reference discloses introducing the prosthetic heart valve 10 using an attachment device 100 or 200, which releasably attaches the stiffening ring 29 of the prosthetic heart valve 10 to a securing device (not shown). Col. 5, lines 41-59. The stiffening ring 29 is positioned within the patient's heart using this tool, whereupon the securing device is actuated to secure the stiffening ring 29 to the patient's heart tissue using a plurality of fasteners 90, i.e., staples 79 or pins 91. Col. 6, lines 51-59. The surgeon then disengages the attachment device 100 from the stiffening ring 29 and removes the attachment device 100 and securing device from the patient's body. Col. 6, lines 59-64. Thus, the Griffin et al. reference discloses using tools, and not elongate attachment devices, to carry a prosthetic heart valve 10 into a patient's heart and then delivering fasteners 90 with the tool to secure the prosthetic heart valve 10.

Turning to the present claims, claim 96 recites a heart valve device that includes an annular body comprising a wall defining a circumference; a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope; and a plurality of elongate attachment devices receivable through the receptacles, each attachment device comprising a detent for self-fixturingly ratcheting through a respective receptacle, the elongate attachment devices having sufficient length such that the annular body can be parachuted down the

elongate attachment devices to an implantation site; wherein each attachment device comprises a plurality of detents spaced apart along a length of the attachment device at an intermediate location between opposite ends of the respective attachment device.

As explained above, the Griffin et al. reference does not disclose, teach, or suggest anything about elongate attachment devices ***having sufficient length such that an annular body can be parachuted down the elongate attachment devices*** to an implantation site, and in fact teaches against such elongate attachment devices. Instead, the Griffin et al. references discloses carrying a prosthetic heart valve into a patient's heart using a tool including an attachment device and a securing device. The disclosed pin 91 cannot satisfy the claimed attachment device since the pin 91 has insufficient length and is incapable of allowing the prosthetic heart valve to be parachuted down it to an implantation site. Instead, the pin 91 is deployed from the securing device only ***after*** the prosthetic valve is introduced using the attachment device.

In addition, the Griffin et al. reference fails to disclose, teach, or suggest an elongate attachment device comprising a plurality of detents spaced apart along a length of the attachment device ***at an intermediate location between opposite ends*** of the attachment device. At most, the Griffin et al. reference discloses a pin 91 that includes a barb 94 on one end of a shaft 98 and a head 92 on the opposite end of the shaft 98. Col. 5, lines 23-25; FIG. 7. In order to secure the Griffin et al. prosthetic heart valve 10 to heart tissue, the pin 91 must be inserted from below the prosthetic heart valve 10 through an opening 96 in the shoulder 57 until the barb 94 exits the opening 96. Thus, the barb 94 must be located at the top end of the pin 91 and not at an intermediate location on the pin 91.

For these reasons alone, claim 96 and its dependent claims are neither anticipated by nor otherwise obvious over the Griffin et al. reference. For similar reasons, claims 1, 32, 37, 74, 113, 116, 117, 119, and 125 and their dependent claims are neither anticipated by nor otherwise obvious over the Griffin et al. reference.

Furthermore, as recited in claims 1, 32, 37, and others, the Griffin et al. reference fails to disclose, teach, or suggest a can or a receptacle in a sewing ring that includes a ratchet tooth or teeth elements for self-ratchetedly engaging the one or more digitations, detents, or pawls on the elongate attachment device received therethrough, as conceded on page 3 of the Office Action.

Although the Colvin et al. reference discloses a suture terminating device 10 positioned inside a valve 30 (allegedly a receptacle or can, as claimed), it would not be obvious to add such a device to the Griffin et al. prosthetic heart valve for at least three reasons. First, as explained above, the Griffin et al. reference expressly ***teaches against using sutures*** to guide and secure a prosthetic heart valve into a patient's heart. The Colvin et al. reference teaches using the disclosed suture terminating devices 10 with ***standard sutures***, and therefore the references disclose mutually exclusive methods for introducing and/or implanting prosthetic heart valves.

Second, a person of ordinary skill would recognize that, even if the Colvin et al. suture terminating devices were somehow mounted in the shoulder 57 of the Griffin et al. prosthetic heart valve, the result would not sufficiently enable use of the disclosed fasteners 90. In particular, the Griffin et al. pin 91 includes a barb 94 that must exit the opening 96 in the shoulder 57 to secure the pin 91 to the upper surface of the shoulder 57, and more importantly secure the prosthetic heart valve 10 to the patient's tissue. When the barb 94 exits the opening 96, it provides visual confirmation to the user that the pin 91 has been properly secured. This would not be the case if

the Colvin et al. suture terminating devices 10 were used, because the user would be unable to verify whether the Griffin et al. pin 91 had entered the Colvin et al. suture terminating devices 10 sufficiently to engage the internal angulated portions 52 or cam members 92 of the Colvin et al. suture terminating device 10. There would be substantial risk that the pins 91 would not be sufficiently engaged, and therefore that the prosthetic heart valve 10 would not be secured to the patient's heart. None of the cited references teaches or suggests how this could be accomplished.

Further, if the pin 91 were engaged prematurely within the suture terminating device 10, there would be substantial risk that the head 92 would be protrude out away from the patient's heart tissue and the prosthetic heart valve, e.g., into the path of blood flow. A person of ordinary skill would recognize that such a protrusion would risk thrombosis, embolism, and/or other problems.

Third, given the cited references, it would not be obvious to use one or more digitations, detents, or pawls on an elongate engagement device in combination with a can or receptacle including a ratchet tooth, e.g., as recited in claims 1 and 32. The Colvin et al. reference discloses suture terminating devices 10 that are intended for use in securing standard sutures. Col. 1, lines 9-12. Standard sutures do not include one or more digitations, detents, or pawls. One of the alleged advantages of the Colvin et al. suture terminating devices 10 is that they allow a user to disengage and reengage a suture received through the suture terminating device. For example, as explained at col. 9, lines 33-43 of the Colvin et al. reference, should a surgeon need to loosen a suture, the free end of the suture can simply be pulled away from the angulated portion of the suture terminating device 10 shown in FIGS. 1-4, and then tension applied to engage the suture again in the locking

mechanism. See also Colvin et al. reference, col. 11, lines 56-60, which describes similar disengagement and reengagement with the respective to suture terminating device 70 of FIGS. 5-8.

A person of ordinary skill would recognize that, if one or more digitations, detents, or pawls were added to the sutures used with the Colvin et al. suture terminating device, this disengagement and reengagement could not be accomplished easily, because the digitations, detents, or pawls would be captured within the suture terminating device. Thus, this combination would undermine one of the intended purposes of the Colvin et al. devices.

Turning to the Duncan reference, this reference is incompatible with either of the Griffin et al. and Colvin et al. references such that it would not be obvious to combine these references. The Duncan reference is directed to fasteners 50 that include a fastening member 60 and a receiver 62 that are adapted to cooperate and compress tissue between them to facilitate healing of a wound. Col. 5, lines 9-18. The fasteners are made from materials that are absorbable by mammalian tissue, col. 6, lines 44-51, presumably because the fasteners are intended to remain within the tissue being treated until they are absorbed by the tissue. Further, the Duncan fastening member 60 includes a plurality of legs 66 that are spaced-part next to each other and adapted to penetrate tissue. The legs 66 include a plurality of teeth or serrations 80 that are received in similarly serrated apertures 76 in the receiver 62.

Thus, the Duncan fastener 50 includes two flat parts intended to sandwich tissue between them until absorbed by the body. Such a fastener is completely incompatible with devices intended for securing prosthetic heart valves to tissue, as disclosed in the Griffin et al. and Colvin et al. references. If such fasteners were used, they would absorb over time, and then release the

prosthetic heart valve from the patient's heart. For these reasons, it would be improper to combine these references to render the present claims obvious.

However, even if it would somehow proper to combine the serrations of the Duncan fastener with either the Colvin et al. suture terminating devices or the Griffin et al. pins, the resulting combination would be ineffective for securing a prosthetic heart valve. As explained above, if the barb 94 of the Griffin et al. pin 91 is not pushed entirely through the shoulder 57 of the Griffin et al. prosthetic heart valve 10, the user would be unable to verify whether the prosthetic heart valve 10 was properly secured to the patient's heart tissue. Further, even if the components included serrations that allowed engagement of the pin at multiple depths of insertion into the shoulder, there would be substantial risk that the head 92 of the pin 91 would protrude into the path of blood flowing through the prosthetic heart valve, which would risk thrombosis, embolism, and/or other problems, as explained above.

Finally, the Duncan reference fails to disclose, teach, or suggest anything about an elongate attachment member having ***sufficient length such that an annular body can be parachuted down the elongate attachment device*** to an implantation site nor ***one or more detents*** spaced apart along a length of the attachment device ***at an intermediate location between opposite ends of the attachment device***, which are also absent from the Griffin et al. and Colvin et al. references. Accordingly, the present claims are not obvious in light of the cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicants hereby petition for any extension of time necessary to make the present response timely. Applicants believe that a one month extension is currently required.

Respectfully submitted,

VISTA IP LAW GROUP LLP

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By /william a. english/
William A. English
Reg. No. 42,515
Attorneys for Applicants

2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (562) 665-3953
Facsimile: (949) 625-8955